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Response under 37 CFR §1.115 **TECH CENTER 1600/29008**
Expedited procedure - Examining Group 1617

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of

Applicant : Michael G. Hayek
Serial No. : 09/291,227
Filed : April 13, 1999
Title : LUTEIN-CONTAINING SUPPLEMENT AND PROCESS FOR ENHANCING
IMMUNE RESPONSE IN ANIMALS
Docket : IAM 467 PA
Examiner : D. Faulkner
Art Unit : 1617

Assistant Commissioner for
Patents
Washington, D.C. 20231
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Susan M. Lima
Agent Reg. No. 38,769

Sir:

REQUEST FOR RECONSIDERATION

This paper is being filed in response to the Office Action mailed April 11, 2000.
Reconsideration and reexamination are respectfully requested in view of the remarks below.

REMARKS

In the latest Office Action, the Examiner maintained the rejection of claims 1-11 under 35 U.S.C. §103(a) as being unpatentable over Jyonouchi et al. in view of Anon, and further in view of the *CRC Handbook of Toxicology*, 1995, p. 11 (newly cited). While the Examiner admits that Jyonouchi et al. do not teach the administration of lutein to cats or dogs as recited in the previously amended claims, he has now cited the *CRC Handbook* for disclosing that "experimental animal models are known to be useful in conditions that mimic human disease", concluding that the administration of lutein to mice as disclosed in Jyonouchi et al. would have led one to expect the immunomodulatory response "to be similarly useful in all mammals". However, this very general statement that animals may be used to study the diseases of humans certainly does not provide any reasonable expectation that the administration of dietary lutein to a

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mouse would also prove effective in a dog or cat. On this record there is no evidence that the prior art recognized that either dogs or cats are able to assimilate dietary lutein in a manner which affects either's immune system. As previously pointed out, neither mouse nor human physiology is the same as dog or cat physiology. This is further supported by the CRC Handbook, which states that "special consideration must be given toward genetic characteristics, nutritional requirements, microbial etiology and life span of the animal, and reproductive, anatomic, physiological, and behavioral characteristics of the species."

Applicant wishes to remind the Examiner that she previously took the position that the one animal is not necessarily a model for all animals, stating that applicant's specification "does not reasonably provide enablement for all companion animals" and that "the determination of additional species for which the claimed process would be useful would require undue experimentation."

None of the cited references, alone or in combination, teach or suggest a process for enhancing immune response in a dog or cat in the claimed dosage, nor do they provide any reasonable expectation of success that their combined teachings could achieve the claimed process. At most, the references offer an invitation to experiment, which is an improper "obvious to try" standard. See *In re Eli Lilly & Co.*, 14 USPQ2d 1741, (CAFC 1990) and *In re Dow Chemical*, 5 USPQ2d 1529 (CAFC 1988). As stated by the Federal Circuit in *Eli Lilly*,

"An 'obvious-to-try' situation exists when a general disclosure may pique the scientist's curiosity, such that further might be done as a result of the disclosure, but the disclosure itself does not contain a sufficient teaching of how to obtain the desired result, or that the claimed result would be obtained if certain directions were pursued."

The situation here is not like the facts in *Lilly* where the prior art explicitly taught that certain compositions produced weight gains in both poultry and cattle. Here, the Examiner is taking the anomalous position that the less specific a reference is, the more it will teach one skilled in the art. The broad and very generalized statement in the CRC Handbook fails to provide the requisite motivation to do what applicant has done.

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For all of the above reasons, applicant submits that claims 1-12, 14 and 16 are in condition for allowance. Early notification of allowable subject matter is respectfully solicited.

Respectfully submitted,

KILLWORTH, GOTTMAN, HAGAN
& SCHAEFF, L.L.P.

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